

Remarks

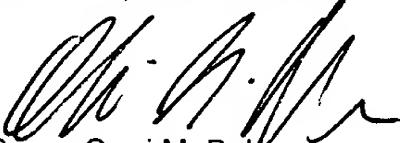
The claims now in the application are claims 1-25, Claims 1 has been amended.

Applicant's undersigned attorney thanks the Examiner for the courtesy of a telephone conference as a result of which the Examiner has agreed to withdraw the art rejections she has made. However she suggested certain amendments to the specification and claims which are set forth herein. Namely, claim 1 should be designated in numbered paragraphs and claim 9 amended to supply a generic description for Miglyol. Furthermore Example 1B should be corrected to remove the inconsistency in columns 2 and 3 where no ranges are given for Miglyol and the castor oil. Applicants have deleted the numbers in these column. Such deletion is not considered to be new matter and it does not affect the scope of the claims. At this point applicants have inserted a definition of Miglyol and the owner of its trademark. Since these insertions are matters of public domain knowledge they are also not considered to be new matter.

As a result of these comments and amendments all claims as amended in the present application are allowable and a prompt passage to issue is respectfully solicited.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the specification

page 11 Example 1 B : Amend the example to read as follows.

B.Cyclosporine Non-Polar lingual spray

	Amounts	preferred amount	most preferred amount
Cyclosporine	1-50	3-40	5-30
Miglyol ®*	[20]	[25]	30-40
Polyoxyethyl-ated castor oil	[20]	[25]	30-40
Butane	25-80	30-70	33-50
flavors	0.1-5	1-4	2-3

*Miglyol is a registered trademark of Huels AG and describes a fractionated coconut oil of boiling point 240-270°C comprising saturated C₈ and C₁₀ triglycerides.

In the claims

Amend Claims 1 and 19 to read as follows

1. (Twice Amended) A buccal spray composition for transmucosal administration of a pharmacologically active compound

provided that

a) where the said active compound is soluble in a pharmacologically acceptable polar solvent said composition comprises in weight % of total composition: aqueous polar solvent 30-99.69%, active compound 0.001-60%,

ai) where said composition in a polar solvent additionally comprises a propellant said composition comprises in total weight % of total composition: a propellant selected from the group consisting of C₃₋₈ hydrocarbon of a linear or branched configuration 2 - 10%, aqueous polar solvent 10-99%, and active compound 0.1-25%,

b) where said active compound is soluble in a pharmacologically acceptable non-polar solvent said composition comprises in weight % of total composition: non-polar solvent 30-99.69%, active compound 0.005-55%, and

bi) where said composition in a non-polar solvent additionally comprises a pharmaceutically acceptable propellant said composition comprises in weight % of total composition: a propellant selected from the group consisting of C₃₋₈ hydrocarbon of a linear or branched configuration 5-80%, non-polar solvent 20-85%, active compound 0.05-50%,

wherein in a), ai), b) and bi) above the active compound is selected from the group consisting of biologically active peptides, central nervous system active amines, sulfonyl ureas, antibiotics, antifungals, antivirals, sleep inducers, antiasthmatics, antiemetics, histamine H-2 receptor antagonists, barbiturates, prostoglandins, bronchial dilators selected from the group consisting of terbutaline, and theophylline.

19. (Twice Amended) The composition of Claim 1 wherein the non-polar solvent is [miglyol] a mixture of saturated C₈ and C₁₀ triglycerides.

The following are examples of each class (all values unless otherwise specified are in weight percent):

EXAMPLE 1

5

Biologically active peptides including peptide hormones

A. Cyclosporine lingual spray

	Amounts	preferred amount	most preferred amount
Cyclosporine	5-50	10-35	15-25
water	5-20	7.5-50	9.5-12
10 ethanol	5-60	7.5-50	10-20
polyethylene glycol	20-60	30-45	35-40
flavors	0.1-5	1-4	2-3

B. Cyclosporine Non-Polar lingual spray

	Amounts	preferred amount	most preferred amount
Cyclosporine	1-50	3-40	5-30
Miglyol ®*			30-40
Polyoxyethyl-ated			30-40
castor oil			
Butane	25-80	30-70	33-50
flavors	0.1-5	1-4	2-3

15

*Miglyol is a registered trademark of Huels AG and describes a fractionated coconut oil of boiling point 240-270°C comprising saturated C₈ and C₁₀ triglycerides.